CARDIAC CATHETERIZATION
REVIEW CRITERIA

(DRAFT as of 9/11/03)

DEFINITIONS

Adult means a person 18 years of age or older.

Capacity means 1500 adult cardiac catheterization procedure equivalents per dedicated and multipurpose room per year. This is based upon the assumption that on the average, a cardiac catheterization service is available 250 days a year for 8 hours per day and that the average laboratory will perform six procedure equivalents per day.

Cardiac Catheterization is an invasive medical procedure performed within a cardiac catheterization laboratory and used as a diagnostic or therapeutic tool for heart and circulatory conditions. During a catheterization procedure a catheter is inserted into a blood vessel and is manipulated by a physician to travel along the course of the vessel into the chambers or vessels of the heart. Imaging equipment is used as an aid in placing the catheter tip in the desired position. Once in place the physician is able to perform various diagnostic and/or therapeutic procedures.

Cardiac Catheterization Laboratory refers to a room or suite of rooms in a hospital, a mobile unit, or a freestanding facility that has the equipment, staff and support services to function as an integrated unit for the purposes of performing cardiac catheterization procedures.

Cardiac Catheterization Patient Encounter means an angiographic or physiologic study or treatment or combination of studies and/or treatments performed in a single session on a single patient in a cardiac catheterization laboratory.

Diagnostic Cardiac Catheterization refers to the performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart, or abnormalities in the heart structure, whether congenital or acquired. Post-operative evaluation of the effectiveness of prostheses also can be accomplished through a diagnostic catheterization procedure.

Patient Encounter Equivalents are used to index all cardiac catheterization procedures to the time that is required for a diagnostic procedure to be performed. In the computation of the use rate (percent of capacity) of authorized adult cardiac catheterization rooms, each adult diagnostic cardiac catheterization and other cardiac catheterizations of similar complexity shall equal a 1.0 patient encounter equivalent. Each therapeutic patient

encounter shall equal 1.5 patient encounter equivalents. A patient who receives both a diagnostic and therapeutic procedure during one visit to the cardiac laboratory is counted as a single therapeutic patient encounter. Each pediatric patient encounter shall equal 2.0 patient encounter equivalents. Each catheter-based electrophysiological (EP) study shall equal 1.5 patient encounter equivalents.

Publicly Available Data means patient encounter counts based upon the most current publicly available data from the Joint Annual Reports of Hospitals and Ambulatory Surgery Treatment Centers (ASTC) and from hospital UB-92 database. For data not included in these data systems, preference should be given to verifiable data sources. All data used in the completion of the application including clear statements of the sources of data should be provided in the application.

Service Area for cardiac catheterization shall mean the geographic area defined in terms of counties represented by the applicant as the reasonable area to which the facility intends to provide services and/or which at least 75% of its recipients reside. At least 75% of the population of a service area for cardiac catheterizations must reside within 60 miles driving distance of the facility.

Therapeutic Cardiac Catheterization refers to the performance of cardiac catheterization for the purpose of correcting or improving certain conditions that have been determined to exist in the heart or great arteries or veins of the heart. This includes Percutaneous Coronary Interventions (PCI) that is catheter-based treatment procedures for relieving coronary artery narrowing. Included within this definition are procedures such as rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents, brachytherapy, and other catheter treatments for treating coronary atherosclerosis.

STANDARDS

The need for cardiac catheterization services shall be based upon the following minimum standards:

1. Each cardiac catheterization laboratory shall project the number of adult diagnostic, adult therapeutic, pediatric, and catheter-based procedures that they will perform annually. The projection should be in actual patient encounters and not diagnostic equivalents and must meet the following minimum numbers within three years of service initiation.

    a. Adult laboratory – 400 diagnostic patient encounters.
    b. Adult laboratory performing therapeutic procedures – 400 therapeutic patient encounters.
    c. Pediatric laboratory – 100 pediatric patient encounters.
    d. Mobile laboratory – 80 patient encounters per year for each day of the week that the mobile unit is operated.

2. A certificate of need proposal to provide new cardiac catheterization services shall not be approved unless the average current utilization for all existing and approved providers is sufficient to equate to 80% of capacity for the service area.

3. The need for a particular service area will be calculated by first counting capacity. For existing services, CON approved but not built cardiac catheterization labs, and all applications under review or appeal, capacity is determined by multiplying the number of cardiac catheterization laboratories by 1500 and then determining 80% of the resulting product. The providers used to determine capacity and utilization shall include all providers located within the service area.

   Each applicant must provide publicly available data to show where all of the residents of the proposed service area who received cardiac catheterization procedures during a defined 12-month period prior to the application went to receive services. These data should include all facilities that provide cardiac catheterization services to residents of the service area, the number of cardiac catheterization patient encounters from the service area for each facility as well as the total cardiac catheterization patient encounters for each facility. The data should be for the most current 12-month period prior to the application date for which data are publicly available. Based on these data, the applicant for the new service must demonstrate the impact on current providers that are serving residents of the same service area.

4. Current utilization shall be counted as the actual number of patient encounters performed in each existing facility plus the proposed volume numbers from the approved CON applications and the CON applications under review. To count actual procedures, diagnostic procedures are counted as a weight of 1, therapeutic procedures are counted as a weight of 1.5, pediatric procedures are counted as a weight of 2.0 and catheter-based electro physiology procedures are counted a as a weight of 1.5.

5. In service areas where no existing cardiac catheterization service exists capacity and utilization will be measured for facilities providing services to residents of those areas as described above. Each applicant shall demonstrate need based epidemiological evidence of the incidence and prevalence of conditions for which diagnostic, therapeutic or pediatric catheterization is appropriate within the proposed service area. The demand for the service is the area should be based on historical utilization in the service area and local, state, and/or national use rates. The applicant must show the data and methodology used to estimate the need and demand for the service.

6. A CON proposal to provide expanded cardiac catheterization services shall not be approved unless existing services within the proponent's facility are demonstrated to be currently utilized at 80% of service capacity.

7. Patient encounter counts should be based upon the most current publicly available data.

8. Staffing –The physician(s) performing the cardiac catheterization procedures should be board certified/eligible in cardiology.

9. The applicant must demonstrate how emergencies within a freestanding cardiac catheterization laboratory, mobile cardiac catheterization, or hospital-based cardiac catheterization laboratory without open-heart surgery capability will be managed in conformity with accepted medical practice. The applicant must have a written transfer agreement with a facility which performs cardiac surgery.

10. An applicant proposing to do only diagnostic catheterization may perform PCI in an emergency (per current American College of Cardiology (ACC) data definition) without on-site cardiac surgery services.

11. An applicant proposing to do elective therapeutic catheterization without on-site cardiac surgery services must perform these services in a facility licensed by the State of Tennessee and shall demonstrate all of the following as well as compliance with all current licensure rules and regulations for the State of Tennessee regarding the provision of cardiac catheterization: (Applicants should also review the most recent guidelines of the American College of Cardiology/American Heart Association in formulating their programs).

    A. The operators must be experienced interventionalists who regularly perform elective intervention at a tertiary facility.

    B. The nursing and technical catheterization staff must be experienced in handling acutely ill patients and comfortable with interventional equipment. They must participate in a 24-hour, 365-day call schedule. They must have acquired experience in dedicated angioplasty labs at a surgical center.

    C. The catheterization lab itself must be well equipped, with optimal imaging systems, resuscitative equipment and intra-aortic balloon pump (IABP) support, and must be well stocked with a broad array of interventional equipment.

    D. The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.

    E. The applicant's administration/management must fully support the program and enable the fulfillment of the above institutional requirements.

    F. There must be formalized written protocols in place for immediate and efficient transfer of patients to the nearest cardiac surgical facility.

G. Primary intervention must be available and performed routinely as the treatment of choice around the clock for patients with acute coronary syndrome, including AMI (per current ACC data definition), to ensure streamlined care paths and increased case volumes.

H. The applicant should have written case selection criteria for the performance of primary angioplasty. Patients with the following clinical presentation are considered at high risk and should be excluded as elective procedure candidates at sites without onsite cardiac surgery backup.

1. TIMI grade 3 flow in the infarct-related artery (IRA) in hemodynamically stable patients without ongoing angina.

2. A patient with greater than 60 percent stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter.

3. In extremely long or angulated infarct-related lesions with TIMI grade 3 flow in stable patients with three-vessel disease.

4. In infarct-related lesions of small or secondary vessels.

5. In lesions other than the IRA (unless they are flow-limiting inpatients with hemodynamic instability or ongoing symptoms).

I. The applicant must insure that the facility has an ongoing program to:

1. Provide for continual education within an affiliated tertiary care facility.

2. Assure ongoing two-way communication between the physicians at the catheterization lab-only site and the cardiologists and cardiovascular surgeons at the back-up site.

3. Compile and evaluate literature regarding the incidence of complications associated with angioplasty performed at other facilities without on-site surgical back up.

4. Demonstrate that the time required to prepare a surgical suite is equivalent to the time required to transport the patient to a nearby site.

5. Develop an efficient transport system.

6. Ensure that the cardiac surgeons communicate outcomes and follow-up results to the patient's primary care physician as well as the cardiologist to ensure continuity of care.

7. Hold in-service educational sessions to update staff on techniques and products.

8. Invest in educational materials, such as instructional CD-ROM for interventional procedures.

9. Involve cardiac surgeons providing back up in the development of selection criteria for primary and elective angioplasty procedures.

10. Maintain a staffing mix of both registered nurses and technicians to have essential assessment and procedural knowledge.

11. Perform primary angioplasty initially on low-risk patients before offering elective angioplasty services in order to demonstrate low complication rates.

12. Seek cardiologists experienced in primary angioplasty to spearhead the move to provide interventional services, as they can provide guidance during complicated procedures.

13. Streamline communication guidelines so that one individual within the referring area is responsible for relaying all information to the back-up surgical site. Provisions within the written transfer agreement should address this communication requirement.

12. Cardiac surgery shall be available on-site for all cardiac catheterization laboratories that perform pediatric procedures of either a diagnostic or therapeutic nature.